

## **REMARKS**

Claims 32-43 and 50-65 are currently pending in the present application. Claims 32, 35, 55, 57 and 58 have been amended herein. No new matter has been added. Claim 32 has been amended to recite that the plastics members form the spring. Claim 35 has been amended to depend from claim 34. Claim 55 has been amended to include a cover member removably secured to the device housing, the cover member covering an end of the device housing. Claim 58, claiming a cover, has been amended to correct antecedent basis. Claims 32, 57 and 58 have been amended to make grammatical corrections. Support for the newly amended claims 32, 55 and 58 may be found throughout the specification and in the originally filed claims. For example, support for the amendment to claim 32 may be found on page 19, lines 6-13.

### **I. Election/Restriction**

As requested by the Examiner, Applicants confirm the generic status of claims 32 and 55, both of which require a lock for releasably locking the plunger.

### **II. Objection to the Specification**

The specification has been objected to as failing to provide antecedent basis for the subject matter claimed in claim 36 wherein the strips and the plunger are molded as a unitary component.

Applicants respectfully assert that the specification provides support for the subject matter of claim 36 wherein the strips and the plunger are molded as a unitary component. For example, as described on page 19, lines 16-19, "Preferably, the strips 336A and 336B are integrally connected with the walls 306 in a moulding process where the plunger 330 and the spring formed from the strips 336A and 336B is formed in one moulding operation." The strips and the plunger molded as a unitary component are also shown, for example, in FIG. 21 A.

Applicants respectfully request that the objection to the specification be withdrawn.

### **III. Objection to the Drawings**

The drawings have been objected to under 37 C.F.R. 1.83(a). According to the Examiner the strips and plunger molded as a unitary component of claim 36 have not been shown.

As discussed above, Applicants respectfully assert that the unitary component including the strips and plunger is shown at least in FIG. 21A.

Applicants respectfully request that the objection to the drawings under 37 C.F.R. 1.83(a) be withdrawn.

### **IV. Double Patenting Rejection**

Claims 32-41 and 50 to 64 have been rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-43 of U.S. Patent No. 6,830,562.

Claims 42, 43 and 65 have been rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-43 of U.S. Patent No. 6,830,562 in view of U.S. Patent No. 5,643,214.

Applicants respectfully assert that the pending claims of the present application are patentably distinct from claims 1-43 of U.S. Patent No. 6,830,562 and also in view of U.S. Patent No. 5,643,214. However, in order to expedite prosecution of the present application, Applicants are filing a terminal disclaimer with this Amendment.

Applicants have amended claim 35 to depend from claim 34 to obviate the Examiner's objection under 37 C.F.R. 1.75 with respect to claim 35 and claim 52 being duplicate claims.

Therefore, Applicants respectfully request that the Examiner withdraw the obviousness-type double patenting rejection.

### **V. Claim Rejections**

#### **A. Claim Rejections Under 35 U.S.C. § 102**

Claims 32-41, 50-57 and 61-64 have been rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,093,172 to Funderburk. According to the

Examiner, Funderburk discloses an injector device having a housing 28/38, lock 58, drive 36, flexible plastic members 56/94, plunger 54, needle 12, tubing and recess 100.

Applicants respectfully traverse the Examiner's rejection based on Funderburk. Applicants respectfully request reconsideration of rejected claims 32-41, 50-57 and 61-64 in light of the claim amendments to claims 32 and 55 and the traversal discussed below.

Funderburk is directed to an injector for placement of an infusion set where the injector includes a safety lock mechanism for retaining the insertion set during advancement of the plunger. (Abstract.) The plunger 30 includes a central drive stem 54. The rearward end of the drive stem 54 is longitudinally split to define a pair of trigger arms 56 which have out-turned trigger fingers 58 on the rearward ends thereof. (See Col. 6, lines 37-42.) When the trigger fingers 58 pass entirely through the bore 68, the spring resilience of the trigger arms 56 is sufficient to spread the trigger fingers 58 so that they engage the shoulder 70. In this retracted plunger position, the drive spring 36 is retained in a compressed and cocked condition. (Col. 6, line 66-Col. 7, line 4.) As shown in FIG. 7, the safety lock arms 94 and their associated lock fingers 100 have a size and shape so that the fingers 100 can engage and retain the hub 18 of the insertion set 14. (Col. 8, lines 11-14.) The drive spring 36 normally biases the plunger 30 toward the advanced position (FIGS. 5 and 7). (Col. 6, lines 56-57.) Clearly, the trigger arms 56 and the safety lock arms 94 taught by Funderburk hold plunger and the insertion set in position and do not bias the plunger toward the advanced position. Funderburk discloses a separate drive spring 36 for biasing the plunger toward the advanced position. Further, as stated by the Examiner, Funderburk does not teach or suggest a cover for the injection device.

In contrast, Applicants' newly amended claim 32 requires a drive including a spring for urging the plunger from the retracted position to the advanced position. As claimed, the drive includes a number of individual flexible plastics members and the plastics members form the spring. Funderburk clearly fails to teach or suggest a number of individual flexible plastics members where the plastics members form the spring for urging the plunger from the retracted position to the advanced position. The elements 56 and 94 of Funderburk identified as flexible plastic members by the Examiner clearly do not form the spring for urging the plunger to the advanced position.

Applicants' newly amended claim 55 requires a cover member removably secured to the device housing, the cover member covering an end of the device housing. As discussed above, Funderburk fails to teach or suggest a cover.

Therefore, Applicants respectfully request that the rejection of claims 32-41, 50-57 and 61-64 under 35 USC §102 (b) as being anticipated by Funderburk be withdrawn.

**B. Claim Rejections Under 35 U.S.C. § 103**

Claims 42, 43, 58-60 and 65 have been rejected under 35 U.S.C. § 103 as being unpatentable over Funderburk in view of Marshall (U.S. Patent No. 5,643,214).

Applicants respectfully traverse the Examiner's rejection based on Funderburk in view of Marshall since the references alone or in combination fail to teach or suggest an injection device including a molded device housing having a plunger, a lock and a drive including a spring wherein the spring is formed from plastics members. Funderburk and Marshall, alone or in combination, also fail to teach or suggest an injection device including either a molded device housing, a cover member releasably secured to the housing, a molded plunger, a lock and a drive and wherein the housing is manually deformable to effect release of the plunger.

Furthermore, Applicants respectfully assert that there is no suggestion in either reference to combine the engagement areas and the cover of Marshall with the injector device of Funderburk as required by § 103.

Even if the teachings of Funderburk and Marshall could be combined, all of the recited elements in Applicants' rejected claims would not be found in the combination.

Marshall is directed to an injection device for ejecting a sequence of doses from the needle of a capsule carried within its barrel-like body. (Abstract.) The device includes a cylindrical barrel 1 comprising two tubes 2 and 3. (Col. 2, lines 33-34.) Near the rear end of the tube 3 there is a release mechanism 26. This comprises two diametrically opposed pads 27 located within apertures in the tube 3 and connected by resilient, flexible webs 28 which spread to embrace the tube 23. These pads 27 are normally proud of the exterior of the tube 3. (Col. 3, lines 20-25.) For injection, the pads 27 are squeezed. This spreads the webs 28 sufficiently for them radially to clear the abutments 25. The spring 29 can

now exert itself and push the tube 23 forward. (Col. 3, line 66-Col. 4, line 3.) A cover 30 is shown in FIG. 6C wherein the cover 30 is connected to the tube 2.

Marshall teaches depression of pads 27 that extend through apertures on opposite sides in the tube 3. Webs 28, shown in FIG. 1, located internal to the outer tube 3, are deformed by contact with the pads 27 to release the locked tube 23 and then the spring 29 can push the tube 23 forward. It is clear from the description and FIGS. 1 and 2 that the tube 3 is not deformed as the internal webs 28 are deformed by the pads 27 to release the tube 23 (plunger). Marshall does not teach or suggest that the device housing itself is manually deformable to effect release of the plunger.

As discussed above, Funderburk is directed to an injector for placement of an infusion set where the injector includes a safety lock mechanism for retaining the insertion set during advancement of the plunger. Funderburk fails to teach or suggest plastics members forming a spring and Funderburk fails to teach or suggest a cover.

In contrast, Applicants claimed invention in claims 42, 43 and 65 require that the plastics members form the spring for urging the plunger from the retracted position towards the advanced position. As discussed above, Funderburk fails to teach or suggest plastics members that form a spring and Marshall cannot make up the deficiencies of Funderburk.

Applicants' claimed invention in claims 58-60 requires a device housing that itself is manually deformable to effect release of the plunger and a cover removably secured to the device housing. As discussed above Funderburk and Marshall, together or individually fail to teach or suggest a manually deformable housing and a cover removably secured to the housing. Further, with respect to claim 55 that has been amended to require a cover removably secured to the device housing, Funderburk and Marshall together or individually, fail to teach or suggest the claimed invention.

Therefore, Applicants respectfully request that the rejection of claims 42, 43, 58-60 and 65 under 35 USC §103(a) be withdrawn.

## **SUMMARY**

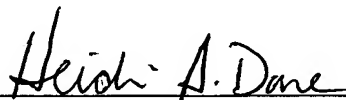
Having carefully addressed all the objections and rejections of the Examiner in the December 13, 2005 Office Action, it is respectfully asserted that the claims properly define

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the invention and that the invention is both novel and non-obvious. Allowance of the present claims is earnestly solicited.

Should the Examiner wish to discuss any of the above submissions in more detail, the Examiner is asked to please call the undersigned at the telephone number listed below.

Respectfully submitted,

A handwritten signature in cursive script, reading "Heidi A. Dare", positioned above a horizontal line.

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